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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/596,159

06/01/2006

Hans Smola

112701-731

2943

29157 7590 10/16/2008  
BELL, BOYD & LLOYD LLP  
P.O. Box 1135  
CHICAGO, IL 60690

EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

10/16/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/596,159 | <b>Applicant(s)</b><br>SMOLA ET AL. |  |
|                              | <b>Examiner</b><br>Kyle Purdy        | <b>Art Unit</b><br>1611             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages (01/08/2007)</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Restriction Requirement*

1. Applicant's election of group I encompassing claims 1-5 in the reply filed on 08/06/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). This requirement is deemed proper and is made final.

2. Claims 1-5 are presented for examination on the merits.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (US 6194379; of record) in view of Gray et al. (US 5714472; of record).**

5. Gray is also directed to nutritional compositions for enhancing wound healing. The composition comprises a carbohydrate, a lipid and a protein source (see abstract). The protein source is to comprise about 28% of the caloric content for the composition (see column 3, line 65; see instant claim 4). The composition is also to have an energy density of at least 1.3 kcal/mL (see column 2, lines 15-20; see instant claim 5). It is taught that a high caloric content is useful because it imparts energy to the user. The composition is also taught to contain proline at a caloric percentage of between 4 and 6% (see column 4, lines 63-65; see instant claims 1 and

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2). It is taught that proline is useful for accelerating and promoting wound healing and tissue repair/cellular division (see column 4, line 55).

6. Gray fails to teach the composition as comprising less than 1.8% of the total calories dues to arginine.

7. McEwen is directed to nutritional formulations comprising a protein source, a lipid source and a carbohydrate source (see Example 1). Example 1 teaches a formulation that comprises sucrose, canola oil and arginine. It is taught that arginine is to comprise about 1% of the total caloric content of the composition (see column 9, lines 1-5; see instant claims 1 and 3). It is noted that the arginine at such a caloric percentage is capable of accelerating wound healing and nitrogen retention after injury.

8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Gray and McEwen with a reasonable expectation for success in arriving at a composition comprising a lipid, a protein and a carbohydrate wherein the composition comprises less than 1.8% of the caloric content is attributed to arginine. One would have been motivated to supplement the teaching of Gray with McEwen because the composition would accelerate the healing of wounds and aid in the retention of nitrogen. Therefore, a composition comprising a protein, a carbohydrate and a lipid wherein the composition attributes less than 1.8% of its caloric content to arginine is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
September 22, 2008*

*/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611*

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |              |
|------------------------|--------------|
| Application Number     | 10596159     |
| Filing Date            | 2006-06-01   |
| First Named Inventor   | Smola et al. |
| Art Unit               | Unknown      |
| Examiner Name          | Unknown      |
| Attorney Docket Number | 112701-731   |

**U.S.PATENTS**

| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|---------------|------------------------|------------|---|--|
| /K.P./            | 1       | 5384308       |                        | 1995-01-24 | Henkin  |  |
| /K.P./            | 2       | 5053387       |                        | 1991-10-01 | Alexander                                       |  |
| /K.P./            | 3       | 5733884       |                        | 1998-03-31 | Barbul et al.                                   |  |

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
|                   | 1       |                    |                        |                  |   |  |

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**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> i | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|-------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|--------------------------|
| /K.P./            | 1       | DE10221403                           | DE                          |                        | 2003-12-04       |   |  | <input type="checkbox"/> |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

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|------------------------|--------------|------------|
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| First Named Inventor   | Smola et al. |            |
| Art Unit               | Unknown      |            |
| Examiner Name          | Unknown      |            |
| Attorney Docket Number | 112701-731   |            |

|        |   |             |    |  |            |  |  |                          |
|--------|---|-------------|----|--|------------|--|--|--------------------------|
| /K.P./ | 2 | EP0764405   | EP |  | 1997-03-26 |  |  | <input type="checkbox"/> |
| /K.P./ | 3 | WO01/78532  | WO |  | 2001-10-25 |  |  | <input type="checkbox"/> |
| /K.P./ | 4 | WO03/075903 | WO |  | 2003-09-18 |  |  | <input type="checkbox"/> |
| /K.P./ | 5 | EP1161945   | EP |  | 2001-12-12 |  |  | <input type="checkbox"/> |
| /K.P./ | 6 | WO03/013487 | WO |  | 2003-02-20 |  |  | <input type="checkbox"/> |
| /K.P./ | 7 | EP0960572   | EP |  | 1999-12-01 |  |  | <input type="checkbox"/> |

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**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>5</sup>           |
|--------------------|---------|---|--------------------------|
| /K.P./             | 1       | Cynober, L., "IMMUNE-ENHANCING DIETS FOR STRESSED PATIENTS WITH A SPECIAL EMPHASIS ON ARGININE CONTENT: ANALYSIS OF THE ANALYSIS," Curr Opin Nutr Metab Care, Vol. 6, pp. 189-193 (2003)  | <input type="checkbox"/> |
| /K.P./             | 2       | Takala, J. et al., "INCREASED MORTALITY ASSOCIATED WITH GROWTH HORMONE TREATMENT IN CRITICALLY ILL ADULTS," N Engl J Med, Vol. 341, No. 11, pp. 785-792, (1999)   | <input type="checkbox"/> |

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/Kyle Purdy/

09/22/2008